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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,754	07/23/2003	Steven M. Leventer	18184-0016CT2	8132

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DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/625,754	Applicant(s) LEVENTER ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. ~~See attached Notice of Non-Compliant Amendment (PTOL-324).~~
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☒ Newly proposed or amended claim(s) 30 and 31 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: none.
 Claim(s) objected to: 30-32, 34 and 35.
 Claim(s) rejected: 28, 29 and 33.
 Claim(s) withdrawn from consideration: _____.

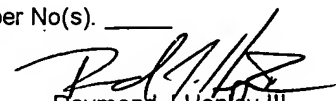
AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
 13. ☒ Other: See Continuation Sheet.

* See "Attachment to Advisory Action"
 * See attached "Notice of References Cited"


 Raymond J. Henley III
 Primary Examiner
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Continuation of 3. NOTE: The amendment will NOT be entered because the signatory page is absent. Also, there lacks a complete listing of ALL claims pending. In an effort to expedite prosecution, the Examiner's comments attached hereto are made in relation to the amendments presently proposed. The claims listed below in Box 7, below, relate to those claims presented in the previous amendment dated May 6, 2005. Note that the status of claims 29-31 has changed from "allowed" to "rejected"/"objected to" for the reasons set forth in the attachment to the present action. The present amendment may be perfected by (i) ratifying the amendment; and (ii) presenting a listing of ALL claims (see 37 CFR 1.121 (C)).

Continuation of 13. Other: see attachment concerning the disposition of the claims presently presented.

ATTACHMENT TO ADVISORY ACTION

On September 21, 2005, an incomplete copy of Applicants' After-Final Amendment filed June 16, 2005 was received by the Office, i.e., it did not contain a signature page. The amendment received on June 16, 2005 was also incomplete, i.e., only the first two pages were received.

Neither of Applicants' above mentioned papers will be entered into the application. The paper submitted September 21, 2005 may be perfected by (i) ratifying the amendment and (ii) presenting a complete listing of all claims as per 37 C.F.R. § 1.121.

In order to expedite prosecution of the present application, the following comments are made with reference to the amendments presented in the most recently filed paper.

Amendment to the Specification

The amendment to the specification at page 19, line 13, i.e., inserting ---at a dose of less than 30 mg/kg--- after "anti-convulsant activity" is noted. However, its insertion at this section of the specification results in it not being used in the same context as it appears in claim 32, i.e., page 19 of the specification concerns the administration of S-tofisopam within the confines of a specific comparative evaluation, while claim 32 is directed to a more general instance of administration.

It is suggested that the expression ----Also, when based on the body weight of the patient, S-tofisopam may be administered at a dosage of less than 30 mg/kg of the patient's body weight.--- be inserted at page 13, line 28 after "...four times a day dosing."

Amendments to the Claims

Upon ratification or re-presentation of the most recently filed amendment, the status of all the claims in the case would be that claims 1-28 and 33-35 have been canceled and claim 32 has been amended. Claims 29-31 would remain as presented in the amendments filed April 20, 2005 and May 6, 2005, (the latter being a formalized version of the 4/20/05 amendment). **Therefore, claims 29-32 would be pending.**

Claim 29 would not be in condition for allowance for the following reasons. In the Office action dated August 16, 2004, (page 3), 250-300 g was offered by the Examiner as the average weight of the animals used by Landry et al. (U.S. Patent No. 6,080,736, col. 21, under the heading "b. animals" and Table 1). It is believed that, given a normal variance of weight that would be present, rats of sufficient weight would have been present in Landry et al. to have placed a composition comprising 10 mg of S-tofisopam in the possession of the public. In particular, because the S-tofisopam composition was administered at a rate of 30 mg/kg, a rat weighing 333.34 g would have had to be present in order for a 10 mg S-tofisopam composition to be present. A weight of 333.34 g is believed to have been within the normal limits of variation given an average weight range of from 250 to 300 g. Therefore, it cannot be concluded that a clear, patentable distinction exists between the composition of present claim 29 and that composition provided for by Landry et al.

Possible New Grounds of Rejection on Appeal

Alternatively, on appeal, the Examiner may introduce the newly cited references "Long Evans Rats", (reference "U" on the attached form PTO-892), "About Rats", (reference "V" on the attached form PTO-892) and "Animal Models-Long Evans

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Outbred Rats", (reference "W" on the attached form PTO-892) in support of a new ground rejection on appeal under 35 U.S.C. § 103. The references show that the average Long Evans rat weights may be "376 plus" grams ("Long Evans Rats", reference "U", first column at the bottom); 270-800 grams for full grown males ("About Rats", reference "V") and just above 400 grams ("Animal Models-Long Evans Outbred Rats" reference "W"). Such would support a conclusion that a rat weighing 333.34 grams, and thus a S-tofisopram composition containing 10 mg (see discussion above), would have been obvious.

It is noted that references "U" and "W" do not have a date of public availability. However, such references could nevertheless be relied on by the Examiner, "References which do not qualify as prior art because they post date the claimed invention *may be* relied upon to show the level of ordinary skill at or around the time the invention was made."(emphasis added)(see MPEP § 2124, last section).

The compositions of claims 30 and 31 are deemed patentably distinct from those provided for by Landry et al. In particular, given that Landry teaches that S-tofisopam was administered at a rate of 30mg/kg, rats weighing from 1.6 kg to 20 kg would be required to meet the requirements of claim 30, i.e., from 50 mg to 600 mg of S-tofisopam, while rats weighing from 3.34 kg to 13.34 kg would be required to meet the requirements of claim 31, i.e., from 100 mg to 400 mg of S-tofisopam. Rats of such weight are clearly not normally encountered.

Respecting claim 32, it is clearly distinguishable over Landry et al. in the form presented in the most recent amendment because a dosage rate of S-tofisopam of less than 30 mg/kg is required therein while Landry et al. teaches a dosage rate of 30 mg/kg.,

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i.e., neither more nor less. Because the S-tofisopam composition of Landry et al. is not useful for the patentees' purposes, one of ordinary skill in the art would have had no motivation whatsoever to modify the rate of administration of the S-tofisopam composition, i.e., to lower the rate to be less than 30 mg/kg, as required by the present claim.

Claim 32, however, remains objected to because it is incomplete, i.e., a therapeutic purpose for which the composition is administered is not set forth in claim. Also, the claim is grammatically cumbersome.

Applicants may wish to consider a claim written as follows in order to place claim 32 in condition for allowance:

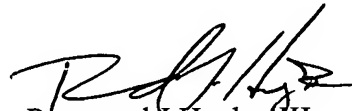
"32. A method of treating convulsions or seizures which comprises administering to a patient in need thereof a pharmaceutical composition comprising an anti-seizure or anti-convulsant effective amount of S-tofisopam, a pro-drug thereof or a pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, and a pharmaceutically acceptable carrier at a dose of less than 30 mg/kg."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III
Primary Examiner
Art Unit 1614

September 22, 2005